BREATHASURE™ DENTAL GUM
CLINICAL TRIAL

REDUCTION OF DENTAL PLAQUE ACCUMULATION
SUMMARY AND CONCLUSIONS

University of the Pacific School of Dentistry Clinical Research Protocol WHOTI G-041

Effect of Frequent Daily Use for Four Weeks of a PXT-20™ Chewing Gum in Reducing Dental Plaque Accumulation When Compared to a Placebo Gum: A Double Blind, Cross-over Treatment Design.

INTRODUCTORY NOTE:

The test gum described below is BreathAsure™ Dental Gum containing PXT-20™. The full report as issued by the University of the Pacific School of Dentistry describes PXT-20™ as MICRODENT®, which is the manufacturer's name of the active ingredient.

PURPOSE:

The purpose of this clinical trial is to compare in normal human subjects the effect on dental plaque accumulation, with normal brushing, of multiple daily uses of a sorbitol-based, sugar-free PXT-20™-containing chewing gum *versus* a placebo chewing gum without the active ingredient (PXT-20™, is a proprietary melt-emulsion of dimethicone in a suitable poloxamer which acts as an agent to both clean and modify the surface free energy of teeth).

PROTOCOL:

Twenty-one healthy subjects with no oral disease and normal toothbrushing skills were instructed to use either a test gum containing PXT-20™, or a placebo gum in a series of two four-week test periods conducted October 5 through December 2, 1998. During the gum test periods, one half of the subjects were assigned each product, then crossed over the following gum test period. Use of product was three times a day after meals. Normal toothbrushing habits were followed.

The plaque was stained just before the baseline examination and each of the two product-use period final examinations. Examinations were scored utilizing an expanded Turesky Modification of the Quigley-Hein Method (Shaver-Schiff). Subjects were instructed to refrain from brushing their teeth on the morning of each examination so that the measurement represented a uniform 12 hour accumulation since last brushing. Subjects were given a rubber cup prophylaxis to reduce plaque to zero at the beginning of each product-use period.

ADVERSE EFFECTS:

No adverse effects on tooth surfaces or soft tissue were noted following any of the Test Chewing Gum product-use periods.

CONCLUSIONS:

BreathAsure™ Dental Gum with PXT-20™ as the active ingredient (Gum Code #100) significantly reduced the accumulation of plaque when compared to the Placebo Gum (Gum Code #50) over the Baseline.

*Overall, BreathAsure™ Dental Gum with PXT-20™ was **35.23% more effective** in reducing the accumulation of plaque than the Placebo Gum when used three times a day for one month with regular brushing.*

SUMMARY AND CONCLUSIONS:

To summarize the data across all trials:

	Whole Mouth Plaque Index Means		Percent Red'n Versus Placebo	Statistical Significance
	Baseline	4-weeks		
Placebo Gum	2.284	2.275	-0.4%	NS
PXT-20™ Gum	2.175	1.400	-35.63%	P<0.0001

Individual Tooth Surfaces
% Plaque Reduction -- Total Scores

	Interproximal	Smooth	Posterior
PXT-20™ Gum	-35.68	-36.36	-33.62
Placebo Gum	-0.80	0.40	-0.80
Statistical Significance	p<0.0001	p<0.0001	p<0.0001

Significant differences, at similar magnitudes of effect, were seen when the tooth surfaces were segregated into Proximal, Smooth and Posterior surfaces and analyzed. The Complete Protocol, Conclusions and Details are presented in the Tabulated Data Section, the Statistical Summaries Section and the Raw Data Section of the full report.

Of particular note is that PXT-20™, the active ingredient in BreathAsure™ Dental Gum, induced excellent plaque reduction on those surfaces where normal toothbrushing habits are typically less effective, i.e. the interproximal and posterior surfaces.

1/1/99

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